

Applicant : Richard M. Broglie et al.
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Attorney's Docket No.: 07148-
025003 / CGL99/0008US04

REMARKS

Claims 25 and 39-44 have been canceled and claims 23, 29, and 37 have been amended without prejudice to continued prosecution. Claim 23 has been amended to recite that the oleic acid content is about 72.5% to about 78.6%. Support for the amendment to claim 23 can be found, for example, in Table 3 of the specification. Claim 29 has been amended to remove recitation of SEQ ID NO:53. Claim 37 has been amended to clarify that the substitution is in the amino acid sequence set forth in SEQ ID NO:53.

New claims 60 and 61 have been added. New dependent claim 60 recites that the linoleic acid content is about 6.4% to about 10.6%. New dependent claim 61 recites that the linolenic acid content is about 4.5% to about 6.5%. Support for new claims 60-61 can be found, for example, in Table 3 of the specification. No new matter has been added. Applicants respectfully request reconsideration and allowance of claims 23, 29, 37, 49-58, and 60-61 in view of the above amendments and following remarks.

The title of this application was amended in the Amendment and Reply to the Action of October 6, 2004, filed on April 6, 2005, to read as: **METHODS FOR INCREASING OLEIC ACID CONTENT IN SEEDS FROM TRANSGENIC PLANTS CONTAINING A MUTANT DELTA 12 DESATURASE**. Applicants request that the Examiner acknowledge this change in the next communication from the patent office.

Applicants have not received initialed copies of the two enclosed Forms (PTO-1449) that accompanied the supplemental information disclosure statements filed April 6, 2005, and July 1, 2005. Thus, Applicants respectfully request that the initialed Forms (PTO-1449) be returned to Applicants in the next communication, indicating that the references have been considered.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 23, 25, 29, 37, 39-44, and 49-58 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserted that the claims are enabled for producing oleic acid levels of 72.5% to 78.6%, linoleic acid levels of 6.4% to 10.6%, and linolenic acid levels of 4.51% to 6.5% but are not enabled for producing oleic acid as high as 90% as recited in claims 23, 39, and 40, seed oleic acid as high as 88% as recited in claims 41-

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42, as low as 1% linoleic acid as recited in claims 25 and 44, or as low as 1% linolenic acid as recited in claim 43.

Applicants respectfully disagree with the Examiner. Applicants will first address the rejection of amended claim 29, which relates to a nucleic acid construct that includes at least one seed-specific regulatory sequence operably linked in sense orientation to a delta-12 fatty acid desaturase coding sequence encoding a delta-12 fatty acid desaturase gene product having at least one mutation which renders the desaturase gene product non-functional. The mutation is a substitution of a Lys residue for Asp in an amino acid region selected from the group consisting of His-Asp-Cys-Gly-His (SEQ ID NO:55) and His-Asp-Cys-Ala-His (SEQ ID NO:54). The Examiner has not provide any reasoning why one of ordinary skill in the art could not make and use the claimed nucleic acid construct.

The specification provides detailed guidance to enable one of ordinary skill in the art to make and used the claimed nucleic acid construct. In particular, the specification describes a number of delta-12 fatty acid desaturase coding sequences and amino acid regions that can be mutated. See, for example, the specification at page 16, line 15 through page 17, line 15. The specification also describes seed-specific regulatory sequences that can be used in a construct. See, for example, the specification at page 18, line 28 through page 19, line 6 and page 21, line 31 through page 23, line 5. The specification also indicates how a nucleic acid construct can be introduced in a plant. See, for example, page 25, line 35 through page 26, line 21 of the specification. Thus, the specification enables one of ordinary skill in the art to make and use the claimed nucleic acid construct without undue experimentation.

The specification also enables one of ordinary skill in the art to practice the methods of claims 23, 25, 37, 39-44, and 49-58. As previously indicated, the results provided in Tables 15 and 16 of Lightner et al. (U.S. Patent No. 6,372,965) demonstrate that oleic acid levels greater than 78.6% can in fact be achieved using a single gene expression strategy. The results of Lightner et al. also demonstrate that linoleic acid levels lower than 6.4% and linolenic acid levels lower than 4.5% can be achieved using a single transgene. See, for example, Tables 14-16 of Lightner et al, in which plant #158-8 has an oleic acid content ranging from 81.3% to 85.56%, a linoleic acid content ranging from 3.02% to 6.3%, and a linolenic acid content ranging from 3.36% to 5.86%. Thus, Lightner et al. demonstrate a dramatic alteration in fatty acid content

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based on a single transgene. This evidence rebuts the Examiner's assertions on page 3 of the Office Action that multiple strategies "were required for dramatic alterations in fatty acid composition in transformed plant seeds" and on page 5 of the Office Action that "mutational inhibition or dominant negative inhibition of gene expression is leaky and requires multiple gene expression inhibition studies to achieve levels of oleic acid in plant seeds such that seed oleic acid levels increase to 90% and linoleic and linolenic acid levels decrease to 1%."

DeBonte and Hitz (U.S. Patent No. 5,850,026, cited in the Information Disclosure Statement of November 7, 2003) provide further evidence that oleic acid levels greater than 78.6% can be achieved using a single gene expression strategy. In particular, Table 2 of DeBonte and Hitz indicates that 82.8% to 86.5% oleic acid was achieved in T4 or later homozygous seeds produced from plants containing a seed specific promoter operably linked in sense orientation to a wild-type or mutant delta-12 desaturase.

Nevertheless, in an effort to expedite prosecution, claims 25 and 39-44 have been canceled and claim 23 has been amended to recite that the oleic acid content is 72.5% to 78.6%. In view of the above remarks, the Examiner is requested to withdraw the rejection of claims 23, 29, 37, and 49-58 under 35 U.S.C. §112, first paragraph, for lack of enablement.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claim 37 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that there was insufficient antecedent basis for the limitation "said mutation" and that SEQ ID NO:23 is not recited in the Markush group of claim 23.

Claim 37 has been amended to recite that the substitution is in a His-Glu-Cys-Gly-His (SEQ ID NO:53) amino acid region. Amended claim 37 is sufficiently definite. The Examiner is requested to withdraw the rejection of claim 37 under 35 U.S.C. §112, second paragraph.

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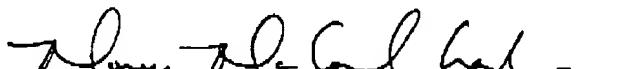
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CONCLUSION

Applicants submit that claims 23, 29, 37, 49-58, and 60-61 are in condition for allowance, which action is requested. The Examiner is invited to telephone the undersigned agent if it is felt that such would advance prosecution of the application. Please apply the Petition for Extension of Time fee and any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 1/17/06



Monica McCormick Graham, Ph.D.
Reg. No. 42,600

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

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